

Remarks

Claims 1-11 are pending in the subject application. By this Amendment, the applicants have amended claim 6. Support for the claim amendments can be found in the specification as originally filed. No new matter has been added by these amendments. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-11 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

The amendments set forth herein have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. These amendments should not be taken to indicate the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claim 6 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. By this Amendment, claim 6 has been amended to clarify what ingredients and amounts fall within the scope of claim 6. In view of the amendments, the metes and bounds of claim 6 can be readily ascertained. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Claims 1-11 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Izvekova *et al.* The applicants respectfully traverse this ground for rejection.

With regard to the antibacterial composition itself, the Izvekova *et al.* reference does not teach or suggest any composition that has the specific energy ratio of carbohydrates, proteins, and fats as required by the claims. Thus, a *prima facie* case of obviousness has not been established because the Izvekova *et al.* reference does not teach or suggest all claim limitations. See, e.g., *In re Zurko*, 258 F.3d 1379, 1385-86 (Fed. Cir. 2001).

Furthermore, evidence that the claimed invention is unexpectedly superior in one of a spectrum of common properties over the prior art can be enough to rebut a *prima facie* case of obviousness. See *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998), *In re Sebek*, 465 F.2d 904, 907 (C.C.P.A. 1972), *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987). The fact that the elements work together in an unexpected and fruitful manner supports the conclusion that the applicants'

invention was not obvious to those skilled in the art. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007); *U.S. v. Adams*, 383 U.S. 39 (1966).

The currently-claimed composition possesses unexpectedly superior growth suppressive effects against Gram-positive bacteria such as, for example, *Staphylococcus aureus* IID 1677 (MRSA), when compared to the neutral liquid diet and acidic fermented dairy products comprised of carbohydrates, proteins and fats present within the ranges of concentrations described in Izvekova *et al.* (Declaration of Dr. Hisae Kume; see also Figures 1-6 of the original application).

Specifically, as can be seen from the data presented in the attached Declaration, the acidic liquid diet of the current invention reduced the *Staphylococcus aureus* IID 1677 cell count after 24-hour incubation from about 4.4×10^7 cells/ml to “less than 10 cells/ml,” which means in the art that cells were undetectable.

In comparison, various acidic fermented dairy products, comprised of proteins, carbohydrates and fats present within the ranges of concentrations described in Izvekova *et al.*, had little or almost no growth suppressive effects against *Staphylococcus aureus* IID 1677. For example, after 24-hour incubation with products other than the claimed composition, the *Staphylococcus aureus* IID 1677 cell count remained as high as about 10^4 to 10^8 cells/ml. Since *Staphylococcus aureus* IID 1677 cells were undetectable after the incubation with the claimed composition, it is readily apparent that the claimed composition possesses unexpectedly superior effects.

With regard to the method for producing the antibacterial composition, the Izvekova *et al.* reference does not teach or suggest the step of sterilizing the mixture after the fermented dairy product is mixed with carbohydrates, proteins and fats. Rather, in Izvekova *et al.*, the fermented dairy product is cooled before mixing with carbohydrates, proteins and fats (column 8, lines 30-36). After the fermented dairy product is mixed with other ingredients, no sterilization at high heat is applied in Izvekova *et al.*

In contrast, the currently-claimed method applies high heat at 100°C for 10 minutes, after the fermented dairy product is mixed with carbohydrates, proteins and fats (specification at page 9, lines 10-11). This high heat treatment kills fermenting microorganisms including lactobacilli in the composition (specification at page 9, lines 10-11).

It is a general understanding in the art that high heat significantly reduces the biological activity of the supernatant of lactobacillus as well as the activity of bacteriocin produced by lactobacillus. See Mezaini *et al.* (Table 3), Abdelbasset *et al.* (Table 3), and Joshi *et al.* (Table 1), showing that heat treatment drastically reduces the antibacterial activity of lactobacillus and bacteriocin produced by lactobacillus.

A skilled artisan would not have modified the Izvekova *et al.* reference, i.e. by sterilizing the composition after the fermented dairy product is mixed with carbohydrates, proteins and fats, to arrive at the currently-claimed invention. The Izvekova *et al.* reference utilizes the antibacterial activity of fermented dairy products for treating or preventing pathogenic infection. Reducing the antibacterial activity of lactobacillus and bacteriocin by sterilization at high heat is unsatisfactory for this intended purpose. Thus, there is no suggestion or motivation to modify the Izvekova *et al.* reference in the manner necessary to arrive at the claimed invention, because such modification would render Izvekova *et al.* unsatisfactory for its intended purpose. See *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984).

It is only the applicants who discovered that, contrary to the prevailing knowledge in the art, the composition maintains its antibacterial effect after sterilization. Furthermore, the composition shows antibacterial effect against both Gram positive and Gram negative bacteria. There is no teaching or suggestion in the prior art regarding the step of sterilizing the mixture after the fermented dairy product is mixed with carbohydrates, proteins and fats.

An assertion of obviousness without the required suggestion or expectation of success in the prior art is tantamount to using the applicants' disclosure to reconstruct the prior art to arrive at the subject invention. Hindsight reconstruction of the prior art cannot support a §103 rejection, as was specifically recognized by the CCPA in *In re Sponnoble*, 56CCPA 823, 160 U.S.P.Q. 237, 243 (1969).

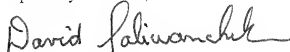
In sum, the applicants respectfully submit that a *prima facie* case of obvious has not been established. Further, the unexpectedly superior anti-bacterial activity of the currently-claimed composition evidences that the applicants' invention is not obvious. Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

In view of the foregoing remarks and the amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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DRS/la/mz

Attachments:

Declaration of Dr. Kisae Kume under C.F.R. 1.132
Copy of the Abdelkader Mezaini *et al.* reference
Copy of the Mechai Abdelbasset *et al.* reference
Copy of the Vmod Kumar Joshi *et al.* reference